

**Remarks:**

Claims 1 to 15, 17 to 26, and 28 to 30 are pending.

Each of independent claims 1, 21, and 28 has been amended to clarify that “each said genetic data is indicative of the presence or absence of a genetic marker” in a particular member. Support for the amendment can be found in paragraphs [0031] and [0032] of the specification as filed.

The Examiner maintains the rejections of claims 1-6, 9-11, 13-15, 17,21, and 28-30 under 35 USC 103(a) as obvious having regard to Parzen, in view of Shattuck-Eidens et al. and Cleveland; and the rejections of dependent claims 7, 8, 12, and 22-26 under 35 USC 103(a) as obvious having regard to Parzen, in view of Shattuck-Eidens et al. and Cleveland, and additionally in view of Kooperberg et al. and Hu. et al. Applicant respectfully traverses these rejections for at least the following reasons.

In particular, the Examiner appears to continue to assert that values representing patient disease status are “genetic data”. The applicant reiterates that, as disclosed in the present application, “medical history of certain diseases” is a non-genetic factor (see paragraph [0035] of the present application). In any event, as now clarified in the claims, indicators of patient disease status, or values representing incidence of disorder, are not “genetic data”, as they are not indicative of the presence or absence of a particular genetic marker in a particular member. Thus, contrary to what is asserted by the Examiner, Shattuck-Eidens et al. fails to disclose or suggest calculating a sum of weighted deviates, where each deviate is weighted by a weight reflecting genetic data associated with that member for whom that deviate is calculated, as claimed in claim 28.

It is further noted that the Examiner is incorrect in stating that Shattuck-Eidens et al. discloses a statistical model for predicting disease risk. In fact, as discussed in the previous response filed on January 27, 2010, the statistical model disclosed in Shattuck-Eidens et al. is used to calculate “the probability of carrying a deleterious BRCA1

mutation”, i.e., the probability that a certain genetic marker is absent or present in the patient (see Shattuck-Eidens et al. at p. 1243, col. 3; and p. 1246, col. 3). The model of Shattuck-Eidens et al. is thus not used to calculate or predict a disease risk. As such, it would not have been obvious for the skilled person to modify the statistical model of Parzen according to Shattuck-Eidens et al. as the two references are directed to different types of calculations.

The Examiner is also incorrect in stating that Shattuck-Eidens et al. discloses or suggests that “sets with the same genetic data have the same weights.” The Examiner relies on the disclosure at p. 1246, col. 2 and 3 of Shattuck-Eidens et al. to support the above statement. However, p. 1246, col. 2 and 3 of Shattuck-Eidens et al. discloses that the log odds,  $L$ , are calculated according to the equation “ $L = -0.08 a + 1.41 b + 0.0 c + 1.29 d + [\dots]$ ”, where “a”, “b”, “c”, and etc, are input data of different factors for each patient. For example, “a is age at diagnosis of breast and/or ovarian cancer” and “d is 1 if patient is diagnosed with bilateral breast cancer but not ovarian cancer, 0 otherwise.” As discussed above, none of the parameters included in this formula is genetic data that is indicative of the presence or absence of a genetic marker. Further, non-genetic data in the same data set of the same patient, such as “a” (age), is weighted by a constant, such as “-0.08”, but not weighted by any data representing a disease status, such as “d”. Thus, this formula provides no support for the Examiner’s above statement, even if disease status were to be considered a genetic data.

Thus, even Parzen were modified according to Shattuck-Eidens et al., the combination still fails to disclose or suggest calculating a sum of weighted deviates, where each deviate is weighted by a weight reflecting genetic data associated with that member for whom that deviate is calculated, as claimed in claim 28.

As discussed in the previous response, the remaining cited references fail to cure the above defects of Parzen and Shattuck-Eidens et al.

The Applicant also reiterates its previous submission that the Examiner has failed to point to any specific disclosure in the cited references for disclosing or suggesting the combined features of predicting disease risk for a member of the population using a model and non-genetic data associated with that member, but weighting the deviate for that member by a weight reflecting genetic data associated with that member, in combination with other features recited in claim 28. The Examiner mischaracterizes that submission at paragraph 2 on page 10 of the present Office Action, and only points to a reference for disclosing one of the combined features. The Examiner appears to dismiss the other noted features by stating that “the claimed statistical model does not specifically use genetic data.” However, it is noted that current claim 28, for example, expressly recites “calculating a sum of weighted deviates” using the genetic data associated with the particular member. Thus, it is respectfully submitted that the genetic data is specifically used in the claimed method, and the cited references, either alone or in combination, fail to disclose or suggest the method of using both genetic and non-genetic data to predict disease risk as specified in claim 28.

Consequently, it is respectfully submitted that the cited references, either alone or in combination, fail to disclose or suggest all of the elements recited in claim 28, and the Office Action has failed to establish a *prima facie* case of obviousness for claim 28.

Likewise, it is respectfully submitted that the Office Action has failed to establish a *prima facie* case of obviousness for any of claims 1-15, 17-26, and 29-30 for the same reasons.

Withdrawal of all of the rejections under 35 USC 103(a) is thus respectfully requested.

In view of the foregoing, favourable reconsideration of the application is respectfully requested.

Application No. 10/634,145  
Docket No. NAA 0018 PA/41049.20  
Response Dated: August 11, 2010

Respectfully submitted,

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